Facsimile of SB/33.

PRE-APPEAL BRIEF REQUEST FOR REVIEW	Docket Number (Optional) ATX-011.03	
	Application Number 10/069,307- Conf. #1962	Filed September 26, 2002
	First Named Inventor Edward P. Ingenito	
	Art Unit 3763	Examiner Q. H. Vu

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant /inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [x] attorney or agent of record. Registration number 44,719
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____

/Dana M. Gordon/
Signature

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August 10, 2009
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

[x] *Total of 1 forms are submitted.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Ingenito, Edward P.	Examiner: Vu, Q.-N. H.
Application No.: 10/069,307	Art Unit: 3763
Filed: 26 September 2002	Atty. Docket No.: **ATX-011.03**
Title: *Tissue Volume Reduction*	

Mail Stop: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Dear Sirs:

Responsive to the Office Action mailed on February 17, 2009 ("Office Action"), the period for reply having been extended to August 17, 2009 by the payment of the fee for a three-month extension of time, and in conjunction with a Notice of Appeal under 37 C.F.R. § 41.31 and the appropriate fee, Applicants respectfully request a pre-appeal brief conference. Pursuant to § 41.31, an appeal is proper in this case because the pending claims have been twice rejected.

I. Rejections under 102(e) or 103(a)

Perkins

Claims 1-3, 13-16, 18-19, 24, 31-34, 55-58, 60-63, 65-67, and 69-72 stand rejected under 35 U.S.C. § 102(e) as being anticipated by or in the alternative obvious over U.S. Patent No. 6,287,290 to Perkins et al. ("Perkins"). Applicant respectfully traverses the rejection.

As an initial matter, Applicant's claims relate to methods of reducing lung volume in a patient by introducing material through a bronchoscope into a diseased alveolar region, where the material induces collapse of the targeted region, promotes adhesion between one portion of the lung and another, and promotes fibrosis in or around the collapsed region of the lung. *Specification* at p. 1, ll. 31 to p. 2, ll. 1-9.

The Office Action contains several factual errors regarding the teachings of Perkins. For example, the Examiner incorrectly states that Perkins discloses "introducing material (gases/liquids/fibrin) through the bronchoscope into a diseased alveolar region within the targeted region." *Office Action* at page 3. As explained in Applicant's response mailed on November 4, 2008 ("Response"), Perkins does not introduce gases/liquids/fibrin to the lung to produce lung volume

reduction. *Response* at pp. 7-8. Rather, Perkins first collapses the lung by aspiration (e.g., by applying a vacuum) or applying an external force. *Perkins* at col. 2, ll. 30-34. The collapsing step may be followed by optionally sealing an air passage leading to the collapsed region of the lung by "deploying a plug within the air passage." *Id.* at col. 2, ll. 34-36; *see also* col. 9, ll. 24-29; col. 10, ll. 37-58; and Figure 4C. Thus, the sealing is performed to prevent reinflation of the already collapsed lung, and does not contribute to the collapse of the lung as the Examiner contends. *See, e.g., Perkins* claim 1.

Importantly, Perkins defines an "air passage" as a "segment of the branching bronchus which deliver[s] to and receive[s] air from the alveolar regions of the lung." *Perkins*, col. 6, ll. 34-39; *see also Response* at p. 8. Exhibit A (Fig. 1-2) of Applicant's Response depicts the human airway system. The left and right bronchi are the two main tubes of the lung that extend from the trachea and branch off within the lung to form secondary and tertiary bronchi. The bronchi further branch to form smaller bronchioles and terminal bronchioles. At the ends of the terminal bronchioles are the alveoli. *Response* at p. 8. Based on the explicit definition of "air passage" in Perkins, and the structure of the human airway system, Applicant submits that Perkins seals at the bronchi before the lung branches into its substructure, well before the alveolar region. Nowhere does Perkins teach or suggest sealing the lung in the alveolar region.

The Examiner also incorrectly states that col. 10, ll. 37-41 of Perkins "further discloses that the method of his invention can be comprises introducing material such as sealing/adhesive material with fibrin glue … the sealing fibrin/glue not only causes collapse the diseased alveolar region but also adhering the collapsed diseased alveolar region…." *Office Action* at p. 3. To the contrary, Perkins never teaches or suggests that a sealing or adhesive material may be introduced into the alveolar region to cause lung collapse or adhering within the alveolar region. In fact, the cited passage of Perkins merely explains that the invention may also include "sealing or occluding the air passage leading to the collapsed tissue."

In summary, Perkins' method of lung volume reduction contemplates first collapsing the lung by aspiration or by applying an external force, followed by optionally sealing the lung with a plug at the level of the bronchi. Perkins does not introduce a material into the alveolar region of the lung, where the material induces collapse, and promotes adhesion and fibrosis, as recited in the present claims. Accordingly, Perkins fails to disclose each and every element of Applicant's claims. For at least these reasons, Applicant respectfully requests the withdrawal of the claim rejections under 35 U.S.C. § 102(e).

Perkins also fails to render the pending claims obvious. As explained above with respect to the § 102(e) rejection, Perkins merely describes collapsing a region of the lung by aspiration or application of an external force, optionally followed by delivering a plug to occlude the "air passage" leading to the collapsed tissue region.

Applicant respectfully contends that the numerous and substantial distinctions between the claimed methods and the teachings of Perkins are beyond the scope of the variations that the Examiner may reasonably characterize as "obvious to try" to one of ordinary skill in the relevant art in light of Perkins. For example, the differences between the claimed methods and the teachings of Perkins cannot reasonably be described as merely selecting a particular species from a well-defined genus of limited scope. Nor can those same differences be reasonably characterized as the result of nothing more than routine experimentation or refinement of what was known in the art. *Response* at p. 9-10.

Applicant further submits that the skilled artisan would have had no reasonable expectation of success in developing the claimed methods in light of Perkins because of the pulmonary phenomenon known as "collateral ventilation." Collateral ventilation occurs when apparently isolated alveolar regions are ventilated through passages or channels that bypass standard airways. As a result of collateral ventilation, a section of a lung targeted for volume reduction via occlusion at the level of an "air passage" still receives airflow due to the presence of auxiliary airways, thereby preventing lung collapse (also called "atelectasis"). Based on their understanding of collateral ventilation, those of ordinary skill in the art would not have viewed the methods of Perkins as effective in producing lung collapse by preventing the targeted region of the lung from receiving air flow. *Response* at p. 10-11.

Exhibit B of Applicant's Response depicts the effects of collateral ventilation on lung volume reduction. Exhibit B consists of four illustrations: 1) normal lung tissue with no collateral ventilation; 2) emphysematous lung tissue with collateral ventilation into which a bronchial plug has been inserted; 3) emphysematous lung tissue with collateral ventilation into the alveolar regions of which a composition comprising a protease has been introduced; 4) and the resulting reduction in volume of the emphysematous lung tissue after such protease treatment. The second illustration demonstrates how collateral ventilation interferes with the method of lung volume reduction disclosed by Perkins. Thus, the second illustration demonstrates that in the method of Perkins the lung can still receive airflow when collateral ventilation is present, thereby preventing atelectasis. *See Response* at p. 11.

Exhibits C and D submitted with the Response further discuss the problematic effects of collateral ventilation in bronchoscopic lung volume reduction therapy. The references explain that collateral ventilation prevents atelectasis when the lung is occluded in the bronchial portion of the airway (i.e., at the level of an "air passage" as defined in Perkins). *See Response* Ex. C, p. 457; and Ex. D, p. 127, col. 2 to p. 128, col. 1. In other words, the Exhibits establish that the skilled artisan would understand that methods like those described in Perkins are generally ineffective in achieving lung volume reduction. Consequently, Applicant respectfully contends that one of ordinary skill in the art would not have had a reasonable expectation of success in developing the claimed methods based on Perkins.

For the reasons set forth above, Applicant respectfully requests withdrawal of the claim rejections under 35 U.S.C. § 103(a) based on Perkins.

Perkins in view of Edwardson

Claims 4-5, 17, 20-21, 25-27, 29-30, 68, and 73 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Perkins in view of U.S. Patent No. 5,739,288 to Edwardson et al. ("Edwardson"). The Examiner alleges that "it would have been obvious to use the fibrin sealant of Edwardson in order to provide an enhanced fibrin formulation for tissue closure thereby improving patient recovery times. *Office Action* at p. 6. Applicant respectfully traverses.

First, Applicant respectfully disagrees with the Examiner's contention that Applicant has attempted to "show non-obviousness by attacking the cited references individually where the rejection is based on a combination of references." *Office Action* at page 7. To the contrary, Applicant has argued that the skilled artisan would not arrive at the claimed invention based on the combination of Perkins and Edwardson because the cited combination does not disclose or render "obvious to try" all of the limitations of the rejected claims. *Response* at p. 12.

At best, using the fibrin sealant of Edwardson in the methods of Perkins might provide the skilled artisan with a material for occluding or sealing leaks in the bronchus leading to the lung after collapse by aspiration. Nevertheless, use of the fibrin sealant in the methods of Perkins would not result in or render "obvious to try" the lung volume reduction methods claimed by Applicant. Therefore, Applicant respectfully asserts that the combination of Perkins and Edwardson does not render unpatentable any of the amended claims. *Response* at p. 12.

Accordingly, Applicant respectfully requests withdrawal of the claim rejections under 35 U.S.C. § 103(a) based on Perkins in view of Edwardson.

Perkins in view of Edwardson and Antanavich

Claims 22-23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Perkins in view of Edwardson, and further in view of U.S. Patent No. 5,814, 022 to Antanavich et al. ("Antanavich"). Applicant respectfully traverses the rejection. Antanavich describes an apparatus for accurately dispensing tissue sealants, one of which sealants may be "an adhesive protein solution having a fibrinogen content of from 3 to 12%." The Examiner asserts that it would have been obvious to one of skill in the art "to provide the composition of fibrinogen from 3-12%, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art." *Office Action* at p. 6.

Applicant respectfully asserts that Antanavich's sole arguably relevant contribution to the Examiner's obviousness rejection is the disclosure of an adhesive protein solution having a fibrinogen content from 3 to 12 %. The combination of Perkins and Edwardson, merely describes delivering a fibrin plug to occlude an air passage leading to a region of the lung ***after*** the lung has been independently collapsed by vacuum aspiration or the application of an external force. *Response* at p. 12-13. The combination of Perkins, Edwardson, and Antanavich does not teach or render "obvious to try" all of the limitations of the claims.

Based on the foregoing, Applicant respectfully requests withdrawal of the claim rejections under 35 U.S.C. § 103(a) based on Perkins in view of Edwardson and Antanavich.

II. Conclusion

In view of the above amendments and remarks, Applicants respectfully request withdrawal of all of the outstanding claim rejections. Applicants believe they have provided for all required fees in connection with the filing of this Request. Nevertheless, the Commissioner is hereby authorized to charge any additional required fees due in connection with the filing of this Request to our Deposit Account, **06-1448** reference **ATX-011.03**.

Respectfully submitted,

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